

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
30 January 2003 (30.01.2003)

PCT

(10) International Publication Number  
WO 03/008030 A2

(51) International Patent Classification<sup>7</sup>: A61M 25/00

(21) International Application Number: PCT/US02/23201

(22) International Filing Date: 18 July 2002 (18.07.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
60/306,178 18 July 2001 (18.07.2001) US  
10/198,261 16 July 2002 (16.07.2002) US

(71) Applicant: ATRITECH, INC. [US/US]; 3750 Annapolis Lane, Suite 105, Plymouth, MN 55447 (US).

(72) Inventor: WELCH, Jeffrey; 4301 Zealand Avenue, New Hope, MN 55428 (US).

(74) Agents: JACKSON, Robert, R. et al.; Fish & Neave, 1251 Avenue of the Americas, New York, NY 10020 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

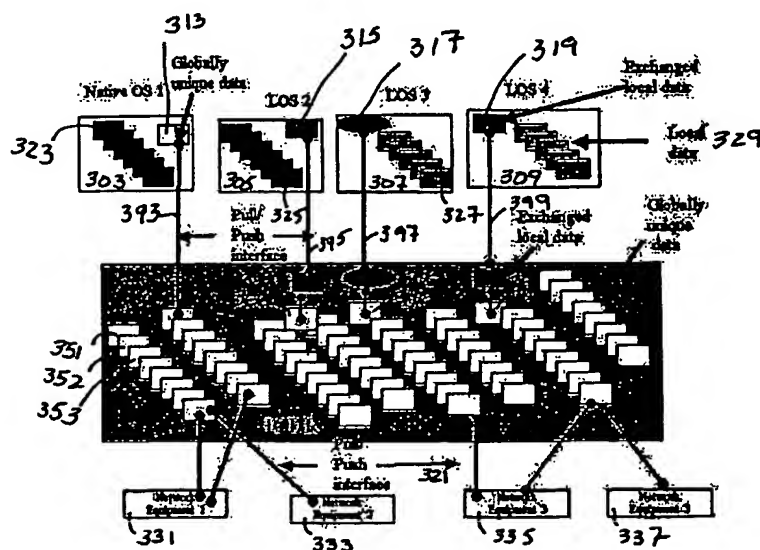
(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CARDIAC IMPLANT DEVICE TETHER SYSTEM AND METHOD



(57) Abstract: Catheterization apparatus for implanting devices is provided with a device tether. The apparatus includes a device delivery tube that provides a pathway for moving implant devices through a patient's vasculature to internal body cavities. The implant devices are carried or pushed through the device delivery tube by a tubular push rod. The implant devices are tethered to a line passing through the push rod lumen. After deployment, the implant devices may be retracted into the device delivery tube for repositioning or retrieval by pulling on the tether.

CARDIAC IMPLANT DEVICE TETHER  
SYSTEM AND METHOD

[0001] This application claims the benefit of U.S.  
5 provisional application No. 60/306,178, filed July 18,  
2001, which is hereby incorporated by reference in its  
entirety herein.

Background of the Invention

Field of the Invention

10 [0002] The invention relates to apparatus for  
implanting devices in atrial appendages. The implanted  
devices may be used to filter or otherwise modify blood  
flow between the atrial appendage and an associated  
atrium of the heart to prevent thrombi from escaping from  
15 the atrial appendage into the body's blood circulation  
system. In particular the invention relates to apparatus  
for percutaneous delivery and implantation of such  
devices.

Description of the Related Art

20 [0003] There are a number of heart diseases (e.g.,  
coronary artery disease, mitral valve disease) that have  
various adverse effects on a patient's heart. An adverse

effect of certain cardiac diseases, such as mitral valve disease, is atrial (or auricular) fibrillation. Atrial fibrillation leads to depressed cardiac output. A high incidence of thromboembolic (i.e., blood clot particulate) phenomena is associated with atrial fibrillation, and the left atrial appendage (LAA) is frequently the source of the emboli (particulates).

[0004] Thrombi (i.e., blood clots) formation in the LAA may be due to stasis within the fibrillating and inadequately emptying LAA. Blood pooling in the atrial appendage is conducive to the formation of blood clots. Blood clots may accumulate, and build upon themselves. Small or large fragments of the blood clots may break off and propagate out from the atrial appendage into the atrium. The blood clot fragments can then enter the body's blood circulation and embolize distally into the blood stream.

[0005] Serious medical problems result from the migration of blood clot fragments from the atrial appendage into the body's blood stream. Blood from the left atrium and ventricle circulates to the heart muscle, the brain, and other body organs, supplying them with necessary oxygen and other nutrients. Emboli generated by blood clots formed in the left atrial appendage may block the arteries through which blood flows to a body organ. The blockage deprives the organ tissues of their normal blood flow and oxygen supply (ischemia), and depending on the body organ involved leads to ischemic events such as heart attacks (heart muscle ischemia) and strokes (brain tissue ischemia).

[0006] It is therefore important to find a means of preventing blood clots from forming in the left atrial appendage. It is also important to find a means to

prevent fragments or emboli generated by any blood clots that may have formed in the atrial appendages, from propagating through the blood stream to the heart muscle, brain or other body organs.

5 [0007] Some recently proposed methods of treatment are directed toward implanting a plug-type device in an atrial appendage to occlude the flow of blood therefrom.

[0008] Another treatment method for avoiding  
10 thromboembolic events (e.g., heart attacks, strokes, and other ischemic events) involves filtering out harmful emboli from the blood flowing out of atrial appendages. Co-pending and co-owned U.S. patent application No. 09/428,008, U.S. patent application No. 09/614,091, U.S. patent application No. 09/642,291, U.S.  
15 patent application No. 09/697,628, U.S. patent application No. 09/932,512, U.S. patent application No. 09/960,749, and U.S. patent application No. 10/094,730, all of which are hereby incorporated by reference in their entireties  
20 herein, describe filtering devices which may be implanted in an atrial appendage to filter the blood flow therefrom.

[0009] Common catheterization methods (including transseptal procedures) may be used to implant the  
25 devices in the atrial appendages. A narrow diameter catheter delivery tube is passed through the patient's vasculature to provide a conduit or pathway to the patient's atrial appendage. The implant devices generally have an elastic or compressible structure.  
30 This structure allows a device to be reversibly compacted to a small size that is suitable for insertion in the narrow diameter catheter delivery tube. A compacted device is attached to a guide wire or a push rod, and

moved through the catheter delivery tube to a deployment position within the patient's heart cavity. Then by remote manipulation, the compacted device may be expanded in situ, and detached from the push rod or guide wire to  
5 serve as an atrial appendage implant.

[0010] The success of the atrial implant treatment procedure depends on the deployment of the implant device in an appropriate position and orientation (relative to the atrial appendage). To be effective the device must  
10 intercept all of the blood flow through the atrial appendage. For example, for a filter device implant to be successful, the device should be positioned and oriented so that all of the atrial appendage blood flow is directed through device filter elements, and so that  
15 there is no seepage around the device.

[0011] However, the percutaneous catheterization delivery techniques used for implant delivery (which often rely on operator dexterity) may not be sufficiently precise to place the device in a desirable orientation at  
20 the first attempt. Inadvertent movement or instability in the position or orientation of the device delivery catheter tube may make precise placement of an atrial appendage implant device difficult. Placing a device in a suitable deployment position with a desirable  
25 orientation may in some cases require repeated position probing or adjustment. Further, properly placed compacted devices, may during subsequent in situ expansion or detachment become dislodged or misoriented. Under some conditions, it may even be desirable to  
30 withdraw a delivered device.

[0012] Co-pending and co-owned U.S. patent application No. 09/932,512 describes a catheterization apparatus having a positioning device or guide, which enables

position probing and readjustment of as-delivered implant device positions. Consideration is now being given to additional catheterization apparatus features to enable controlled recovery or repositioning of implanted devices.

#### Summary of the Invention

[0013] The invention provides a catheterization apparatus having a system by which implant devices are attached to a tether during device delivery and deployment. The catheterization apparatus includes a delivery tube that provides a conduit or a pathway for moving implant devices through a patient's vasculature to internal body cavities. The implant devices may be moved through the delivery tube, and expelled or released from the distal end of the delivery tube for deployment in the internal body cavities. Conventional mechanisms such as a tubular push rod or shaft may be used to move a device through the catheter delivery tube.

[0014] The tether system provides remote mechanical control over implant devices, which are expelled or released from the distal end of a catheter delivery tube into the internal body cavities of a patient. This mechanical control over post deployment devices enables a physician to recover and reposition implant devices as needed.

[0015] In one embodiment of the invention, the tether system includes a wire-dispensing hub connected to the device push rod or shaft. The tether system may be used with implant devices that have (or those that can be fitted with a suitable wire-connection feature, for example, an eye hole. A flexible wire (or line) is dispensed by the hub. The dispensed wire is threaded

through push rod and the implant device wire-connection feature to form a wire loop. A wire leg of the loop extends from the hub, through the tubular device push rod, to the implant device. Another wire leg extends  
5 from the implant device back to the hub. The hub may have an anchor post or fixture to which a wire end may be attached or fixed to securely anchor one leg of the wire loop. The hub also may have other securement means, for example, an adjustable line lock, to hold the other  
10 "free" leg of the wire loop as needed during the implant catheterization procedure.

[0016] During the implant procedure, the tethered implant device is moved through the catheter delivery tube using the push rod. Additional lengths of wire may  
15 be dispensed to lengthen the wire loop as the implant device is moved through and out of the catheter delivery tube if needed. The implant device remains attached or tethered to the wire loop even after it has been expelled from the catheter delivery tube and is deployed in a body  
20 cavity.

[0017] Deployed implant devices, which, for example, are not satisfactorily positioned, may be retracted into catheter delivery tube by retracting the push rod with both wire legs securely anchored in the hub. The  
25 retracted device may be redeployed or may be completely withdrawn as appropriate. Implant devices which are satisfactorily deployed may be untethered by first deactivating the line lock in the hub to free one wire end of the loop, and by then retracting the push rod so  
30 that the free end of the wire loop slides clear of the implant device wire connection feature.

[0018] Other embodiments of the tether system may have other configurations of wires (and wire securement

means), which allow mechanical control over a tethered implant device.

[0019] Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description.

#### Brief Description of the Drawings

[0020] FIG. 1 is a partial cross sectional view of a heart illustrating a conventional catheter entering a left atrial appendage using a transseptal catheterization procedure.

[0021] FIG. 2 is a schematic cross-sectional view of a catheterization apparatus having a device tether system, which includes a wire-dispensing hub connected to a tubular push rod that is used for moving an implant device through a catheter delivery tube in accordance with the principles of the invention. Also, an exemplary filter implant device tethered to a wire loop is shown deployed in an atrial appendage. The two wire legs of the wire loop are, respectively, shown as being anchored at an anchoring post and at a line lock mechanism in the wire-dispensing hub

[0022] FIG. 3 is a schematic cross-sectional view of a catheterization apparatus of FIG. 2 showing the line lock mechanism deactivated to release a leg of the wire loop in preparation for untethering the deployed implant device in accordance with the principles of the invention.

30

#### Description of the Preferred Embodiments

[0023] Implant devices for filtering or otherwise modifying blood flow between an atrial appendage and its



atrium may be attached to a push rod or shaft, and then be percutaneously delivered to the appendage through a catheter delivery tube inserted in a blood vessel leading to the heart.

5 [0024] FIG. 1 illustrates, for example, catheter 21 inserted through a femoral vein (not shown) entering the right atrium of the heart through the inferior vena cava 18, and then passing into left atrium 11 through the fossa ovalis 19 or through the septum 29 before entering  
10 the left atrial appendage 13. Alternatively (not shown in FIG. 1), catheter 21 may enter the left ventricle 16 of the heart through the aorta 12, and then pass through mitral valve 17 to reach left atrial appendage 13. An implant device (not shown) attached to catheter 21 may be  
15 used to prevent thrombus 30 or emboli generated therefrom from migrating into atrium 11.

[0025] The implant devices generally include materials having suitable properties (e.g., radio-opacity) that make it possible to monitor the in-vivo device position  
20 during and after the catheterization procedure using external imaging techniques such as radiography or fluoroscopy, echocardiography, and ultrasound. However, the circuitous path of the catheter delivery tube through the patient's vasculature across the cardiac septum may  
25 make precise placement of an implant device difficult, even when the operating physician has the benefit of using external imaging techniques to monitor the implant device position during the catheterization procedure.

[0026] The present invention provides catheterization  
30 apparatus having a device tether system in addition to the conventional features of known catheterization apparatus (e.g., previously disclosed catheterization apparatus described in U.S. patent application No.

09/960,749, and U.S. patent application No. 60/351,898). A basic feature common to known catheterization apparatus is a device delivery tube, which provides a conduit or pathway for insertion of the implant device into the patient's body. Another basic feature common to known catheterization apparatus is a mechanism such as a push rod or shaft for carrying or moving the implant device through the delivery tube. It will be understood that the inventive catheterization apparatus may in general have one or more nested tubes, wires or shafts, and other features (e.g. the positioning guides that are described in U.S. patent application No. 09/960,749). However for clarity in the description of the present invention herein, and to simplify understanding of the invention, reference will be made only to the two previously mentioned basic conventional features of the inventive catheterization apparatus.

[0027] In the inventive tether system, the implant device is tethered to a length of flexible line or wire extending through a tubular push rod or shaft. The tether wire allows an operating physician to retain mechanical control over an implant device after it has been expelled from the catheter delivery tube into a body cavity. This mechanical control over post deployment devices enables the physician to recover and reposition implant devices as needed.

[0028] The tether system may be used with implant devices that have (or those that can be fitted with) a suitable wire connection feature such as an eye hole. It will also be understood that the device materials have suitable properties (e.g., radio-opacity) that make it possible to monitor the in-vivo device position during and after the catheterization procedure using external

imaging techniques, for example, radiography or fluoroscopy, echocardiography, and ultrasound. Exemplary devices, which may be implanted using inventive tether system, are the reversibly expandable filter implant

5 devices having elastic structures described in U.S. patent application No. 09/428,008, U.S. patent application No. 09/614,091, U.S. patent application No. 09/642,291, U.S. patent application No. 09/697,628, U.S.

10 patent application No. 09/932,512, U.S. patent application No. 09/960,749, and U.S. patent application No. 10/094,730. It will be understood that the tether system may also be used with any other type or kind of implant devices, which are amenable to

15 delivery through catheter tubes.

[0029] In one embodiment of the invention, the tether system includes a wire-dispensing hub connected to the distal end of the tubular push rod or shaft. A flexible wire (line, cord, or string) is dispensed in the hub.

20 The wire may be made of any suitable material, for example, metals, polymers or a combination thereof. A wire of suitable strength may be fabricated from a single strand or from multiple strands of material. The wire passes through the tubular push rod and out of the

25 proximal end of the push rod. The dispensed wire extending out of the push rod is threaded through the implant device wire-connection feature, and passed back through the push rod to the hub. The wire loop thus formed has a wire leg extending from the hub to the

30 implant device, and another leg extending from the implant device back to the hub. Both ends of the wire loop may be anchored or fixed securely at anchoring fixtures that are provided in the hub. The tethered

device may be held firmly against (and carried on) the distal end of the push rod by suitably adjusting the length of the wire loop legs.

- [0030] In a catheterization implant procedure, the push rod carrying a tethered device on its (push rod's) distal end may be used to transfer the implant device from outside the patient's body into a body cavity through a pathway formed by the catheter delivery tube. The implant device may, for example, be a self-expanding device. The device is deployed in the body cavity by pushing it through past the distal end of the catheter delivery tube. The implant device remains tethered to the wire loop even after it has been expelled from the catheter delivery tube.
- [0031] External imaging techniques may be used to verify the position of the deployed device. Alternative diagnostic means, for example, electronic monitoring of the patient's physiological parameters may also be used to assess the suitability of the deployed device.
- [0032] Deployed implant devices, which, for example, are not satisfactorily positioned or oriented, may be retracted into catheter delivery tube by pulling the push rod out of the catheter delivery tube. The backward motion of the push rod causes the wire loop to mechanically pull the tethered device into the catheter delivery tube. Because of its elastic structure the implant device is compressed to its compact size as it is retracted into the delivery tube. The operating physician may attempt to reposition and redeploy the retracted device in a more satisfactory position or orientation by moving the push rod forward to again expel the retracted device from the catheter delivery tube. Before attempts to redeploy the retracted device are

made, the catheter delivery tube itself may be suitably repositioned or stabilized as necessary.

[0033] Alternatively, if medically appropriate, the retracted device may be retrieved from the patient's body  
5 by pulling back the push rod completely out of the catheter delivery tube.

[0034] Implant devices which are satisfactorily deployed may be untethered by first deactivating the line lock in the hub to free one wire end of the loop, and  
10 then retracting the push rod so that the free end of the wire loop slides clear of the implant device wire connection feature.

[0035] FIG. 2 schematically illustrates portions of catheterization apparatus 200 having a device tether  
15 system. Catheterization apparatus 200 includes a hollow tubular shaft or push rod 210, and a catheter device delivery tube 205. Catheter delivery tube 205 and push rod 210 may be fabricated from any suitable material including metals and polymeric materials, for example,  
20 stainless steel and PTFE (e.g., Teflon). Catheter delivery tube 205 may be used to establish a percutaneous passage to a body cavity. Push rod 210 is designed to slide through catheter device delivery tube 205. Push rod 210 may be used to push or carry a compacted implant  
25 device through the device delivery tube 205 into a body cavity.

[0036] For example, FIG. 2 schematically shows delivery tube 205 forming a conduit to atrium 235.  
Further, FIG 2 shows filter implant device 230, which has  
30 expelled through device delivery tube 205, and deployed in a patient's left atrial appendage 240. Implant device 230 is provided with a eye hole 235 at its distal end.

[0037] A wire-dispensing hub 220 is mechanically connected to the proximal end of push rod 210. Hub 220 has a container-like structure, and may be fabricated from any suitable materials including metals and polymeric materials. Wire post 224 and line lock fixture 222, are disposed on an interior wall of hub 220. Line lock fixture 222 includes posts 222a, 222b, and 222c. Hub 220 may be provided with a removable access cover (not shown) to provide access to the interior of hub 220.

[0038] Implant device 230 is tethered by cable 280. Cable 280 is fixed to wire post 224, for example, by a conventional screw and washer arrangement (not shown). Cable 280 may, for example, be a polyester or nylon string. Alternatively, cable 280 may be fabricated from other suitable natural or synthetic fibers. Cable 280 extends from wire post 224 through push rod 210 lumen to implant device 230. Cable 280 passes through eye hole 235 disposed on device 230, and returns through push rod 230 lumen to hub 220. The return end of cable 280 may be wrapped around line lock posts 222a-222c, to anchor cable 280, and to thereby firmly tether implant device 230 on the distal end of push rod 210. In alternative designs of hub 220, line lock 222 may include moving levers, reels, rollers, or other mechanical structures to grip, pinch, or other wise hold and anchor the return end of cable 280. In this fashion, implant device 230 is tethered by the wire loop that is formed by cable 280 with leg 280a extending from wire post 224 to implant device 230, and leg 280b extending from the device 230 to hub 220. Implant device 230 remains tethered after it has been expelled from catheter delivery tube 205 and deployed in atrial appendage 240, as shown in FIG. 2.

[0039] To untether implanted device 230, the end of leg 280 may be unwrapped from around posts 222a, b and c, to free leg 280b from line lock 222. Push rod 210 (with connected hub 220) may then be pulled back out of catheter delivery tube 205. This back ward movement causes cable 280 to slide out of eye hole 235 and to thereby untether device 230. Fig. 3 schematically illustrates the portions of catheterization apparatus 200 shown in FIG. 2 during the untethering procedure. In FIG. 3, cable leg 280b is shown as free and unattached to line lock 222. Push rod 210 is shown as having moved back into catheter device delivery tube 205, and disengaged from device 230. Further, back ward movement of push rod 210 into catheter device delivery tube 205 would cause the free end of cable 280 to completely slide out of eye hole 235 (not shown).

[0040] It will be understood that the foregoing is only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. It will be understood that terms like "distal" and "proximal", "forward" and "backward", "front" and "rear", and other directional or orientational terms are used herein only for convenience, and that no fixed or absolute orientations are intended by the use of these terms.

Claims

1. A catheterization apparatus for implanting a device in an internal body cavity, comprising:
  - a delivery tube for establishing a conduit for passage of said device to said body cavity;
  - a push rod for moving said device through said a delivery tube; and
  - a releasable tether attached to said device for mechanical control over said device after it has been placed in said body cavity.
2. The apparatus of claim 1 wherein said push rod comprises a hollow tube.
3. The apparatus of claim 1 wherein said tether comprises material selected from the group of metals, polymers, natural fibers, synthetic fibers and any combination thereof.
4. The apparatus of claim 1 wherein said push rod is connected to a hub disposed on an end of said push rod, and wherein said tether extends from said hub to said implant device disposed on the other end of said push rod.
5. The apparatus of claim 4 wherein said hub comprises a wire-anchoring fixture, and wherein said tether comprises a wire loop with a wire end secured at said wire-anchoring fixture.



6. A method for positioning a catheter-implanted device in a body cavity, comprising:  
providing a catheterization apparatus comprising:  
a delivery tube;  
a push rod for moving said device through said a delivery tube; and  
a releasable tether attached to said device for mechanical control over said device after it has been placed in said body cavity;  
using said delivery tube to establish a conduit for passage of said device to said body cavity;  
attaching said tether to said device,  
using said push rod to move said tethered device through said delivery tube; and  
expelling said tethered device into the body cavity.

7. The method of claim 6 further comprising detaching said tether.

8. The method of claim 6 further comprising assessing the position of said expelled device.

9. The method of claim 8 further comprising using said tether to mechanically retract said expelled device back into said delivery tube.

10. The method of claim 8 further comprising expelling said retracted device in said body cavity to reposition said device.

11. The method of claim 6 wherein said providing a catheterization apparatus further comprises providing said push rod with a hollow tubular structure.

12. The method of claim 6 further comprising releasably anchoring said releasable tether at one end of said push rod.

13. An apparatus for implanting a device in an atrial appendage, comprising:

a delivery tube for establishing a conduit through the body's vasculature for passage of said device to said atrial appendage;

a shaft for transporting said device through said delivery tube, wherein said shaft comprises a device tether for mechanical control over said device after it has been placed in said body cavity.

14. The apparatus of claim 13 wherein said shaft comprises a hollow tube.

15. The apparatus of claim 13 wherein said tether comprises material selected from the group of metals, polymers, natural fibers, synthetic fibers, and any combination thereof.

16. The apparatus of claim 13 wherein said shaft is connected to a hub disposed on an end of said shaft, and wherein said tether extends from said hub to said implant device disposed on the other end of said shaft.

17. The apparatus of claim 16 wherein said hub comprises a wire-anchoring fixture, and wherein said tether comprises a wire loop with a wire end secured at said wire-anchoring fixture.

18. A method for implanting a device in an atrium's appendage, comprising

providing a catheterization apparatus comprising:

a delivery tube for establishing a conduit through the body's vasculature for passage of said device to said atrial appendage;

a shaft for transporting said device through said delivery tube, wherein said shaft comprises a device tether for mechanical control over said device after it has been placed in said atrial appendage;

percutaneously advancing said delivery tube through a blood vessel to said appendage;

attaching said tether to said device;

using said shaft to move said tethered device through said delivery tube; and

expelling said tethered device into said appendage.

19. The method of claim 18 further comprising untethering said expelled device.

20. The method of claim 18 further comprising assessing the position of said expelled device.

21. The method of claim 20 wherein said assessing comprises using an external imaging technique.

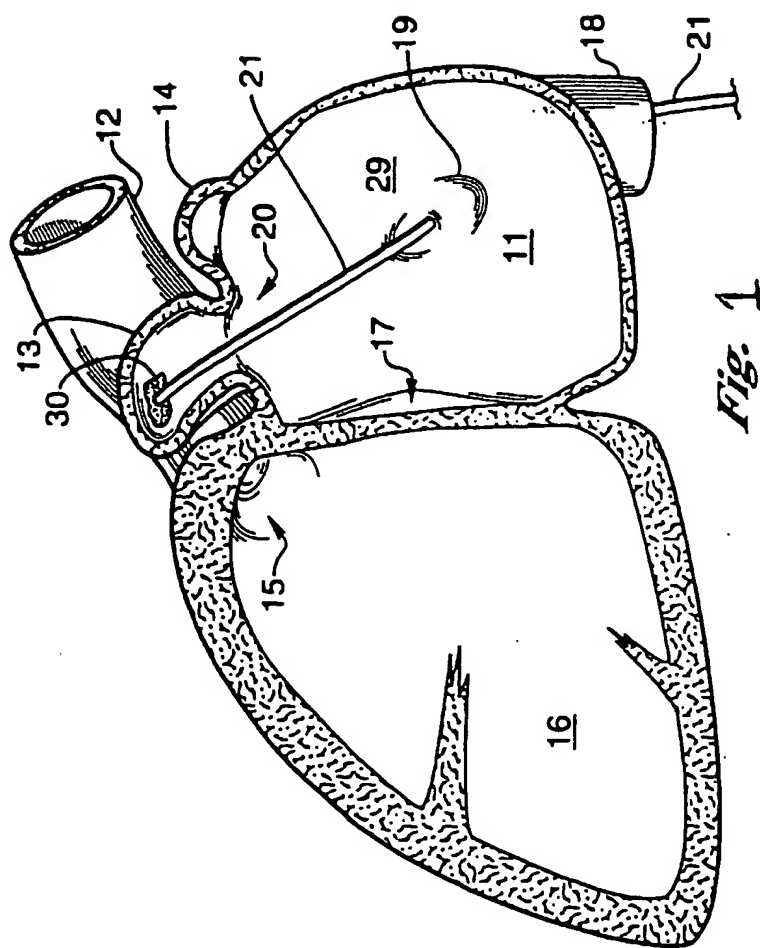
22. The method of claim 21 further comprising using said assessing to decide to retract said expelled device into said delivery tube.

23. The method of claim 18 further comprising using said tether to mechanically retract said expelled device back into said delivery tube device.

24. The method of claim 23 further comprising expelling said retracted device in said appendage to reposition said device.

25. The method of claim 18 wherein said providing a catheterization apparatus further comprises providing said shaft with a hollow tubular structure.

26. The method of claim 18 further comprising releasably anchoring said tether at one end of said push rod.



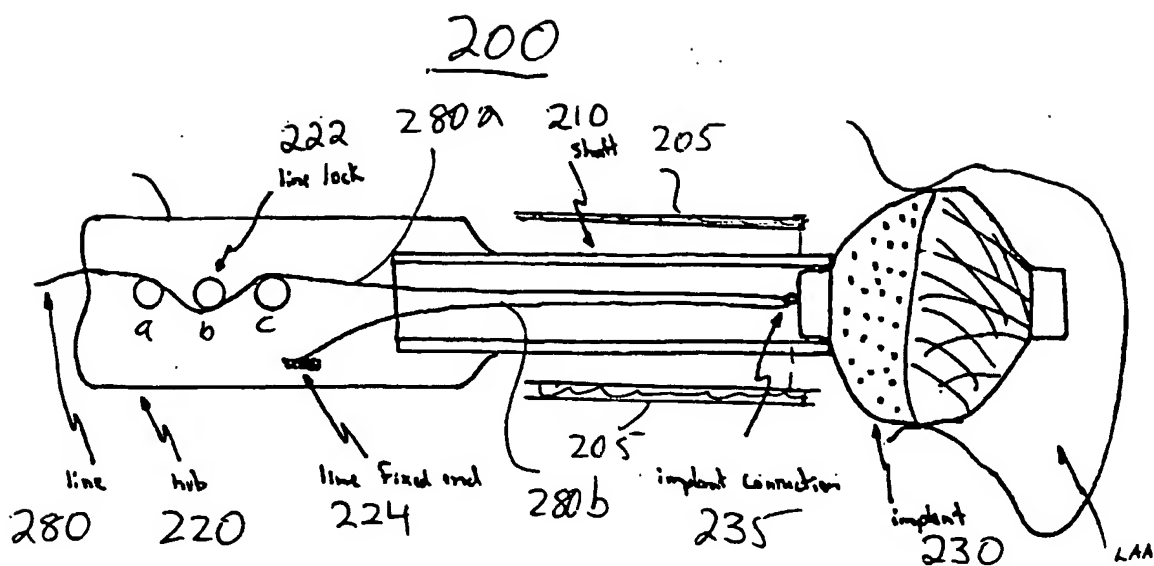


Figure 2 - Before Release

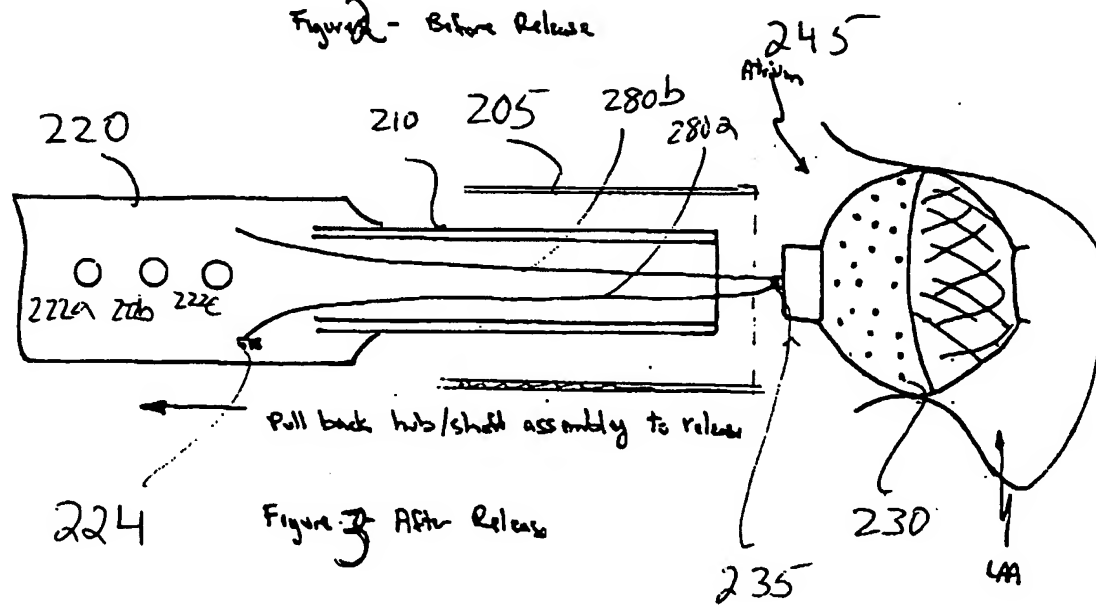


Figure 3 After Release